

REMARKS

Claims 1-5, 7-11 and 13-17 are pending in the application.

Claims 1, 7 and 13 are amended above to overcome the examiner's section 112 rejections and/or to further distinguish the claimed invention from the prior art. In particular, the claims have been amended to include the statement that the method may be used to grade tubules which may be any of round, oval, cylindrical or irregularly shaped. Support for this claim amendment is found at least on page 7, line 14 of the International application. Claims 1, 7 and 13 are also amended to include the feature step a that the first objects are processed so as to fill in any holes therein. Support for this amendment is found at least at page 10, line 8 of the International application. Finally, claims 1, 7 and 13 are amended to include the limitation in part (d) that the second object have a ratio parameter that is calculated in step iii) of at least 0.03 inches. Support for this amendment is found at least page 14, lines 10-15 of the International application. Claims 13-16 are also amended above to overcome the examiner's Section 112, first paragraph rejection.

No new matter is added to the application by way of these amendments.

I. THE SECTION 112, FIRST PARAGRAPH REJECTION OF CLAIMS 13-17

The examiner rejected claims 13-17 under the first paragraph of Section 112 for failing to comply with the written description requirement.

The examiner's rejection has been overcome by amending claims 13-17 to direct them to a computer software product comprising a "carrier medium including a computer program recorded thereon ...".

II. THE SECTION 112, SECOND PARAGRAPH REJECTION OF ALL CLAIMS

The examiner rejected claims 1-5, 7-11 and 13-17 under the second paragraph of Section 112 for being indefinite. In particular, the examiner takes the position that the use of the word "medium" at step (d) part (v) is indefinite.

The examiner's rejection is overcome by independent claims 1, 7 and 13 to recite a minimum hole size for counting as first objects.

III. THE OBVIOUSNESS REJECTIONS

A. The Rejection of Claims 1, 3-5, 7, 13 and 15-17 For Obviousness Over Cheng

The examiner rejected claims 1, 3-5, 7, 13 and 15-17 for being obvious over Cheng et al. It is the examiner's position that Cheng discloses all of the features of rejected independent claims 1, 7 and 13 except for explicitly teaching a method of providing a second and third image. Regarding this missing teaching, the examiner takes the position that Cheng suggests the second image by teaching enhancing the first image by distinguishing first objects in the first image and that Cheng suggests the third image by teaching filtering the distinguished second objects, i.e. rough textures. Moreover, the examiner takes the position that "it would have been obvious to one of skill in the art at the time of the invention to have provided second and third images as claimed in the method taught by Cheng et al. for grading tubules in digitized images of microscopic slides of breast cancer malignancies. . . because storing the data being processed in image analysis , i.e. providing, for further image analysis steps is part of the routine process of image analysis." (See page 9 of the Office Action).

As the Applicant will demonstrate below, all pending application claims are non-obvious in view of Cheng because: (1) the newly added claim features are not disclosed or suggested by Cheng; and (2) Cheng does not disclose or suggest many features of independent claims 1, 7 and 13.

1. Claims 1, 7 and 13 are amended above in a manner that causes them to be non-obvious and patentable

Independent claims 1, 7 and 13 are amended above to require that the first objects detected in the first image are "processed so as to fill in any holes therein" in the second image. The image of Cheng is not processed in this manner. Therefore, all claims are non-obvious and patentable at least because Cheng does not disclose this new feature of every pending claim.

2. The claimed images are not disclosed or suggested by Cheng

The examiner's obviousness rejection must be withdrawn because many other claim features are not disclosed or suggested by Cheng. The examiner seems to misunderstand the Applicant's position regarding the differences between the claimed invention and Cheng in the context of the production of three different images. The Applicant does not disagree with the examiner's proposition that the creation of multiple images in an analysis method is known or would be apparent to one skilled in the art at the time of the invention. Instead, what the

Applicant has demonstrated is that the claimed images, and in particular, the second image, contains information that is different and not present in any Cheng image. This is but one of many differences between the claimed invention and the methods disclose in Cheng that cause all pending claims to be non-obvious and patentable over Cheng.

In particular, all pending claims are not obvious because Cheng does not disclose or suggest:

- a) processing the first image twice, i.e. in two different ways, to yield second and third images and distinguishing different types of image features (first and second objects) using the different images. (claim 1 paragraphs a) and b)). In Cheng, the focus is always upon characterizing the same objects;
- b) combining data from the second and third images to identify as holes within tubules second objects contained within first objects by excluding objects not indicated to have epithelial layers and first objects not containing second objects. (See, e.g., claim 1 step b). Cheng does not disclose t ; and
- c) Since Cheng only counts tubule hole area, it does not count potential tubules (“first objects”) or the area of the tubule epithelial layer, or distinguish single holed tubules from multi-holed tubules. Unless fortuitously and by some undisclosed means Cheng only receives histological specimens in which multi-holed tubules are absent, Cheng cannot:
 - i) count the number of tubules (e.g., claim 1 steps (d)(i),
 - ii) express the number of tubules as a proportion of the number of potential tubules (e.g., claim 1 step (d)(ii),
 - iii) determine the ratio of the area of each tubule hole to that of its respective tubule (e.g., claim 1 step (d)(iii),
 - iv) determine the ratio of tubule hole total area to tubule total area (e.g., claim 1 step (d)(iv), or
 - v) count tubules containing at least holes having a ratio parameter of at least 0.03 (e.g., claim 1 step (d)(v).

a. Cheng does not disclose processing images to identify objects in different images

As previously discussed, Cheng does not read on to claim 1 part a). Regarding this claim feature, the examiner's position ignores a significant feature of the claims and that is the nature of the objects in the images. In the second image, the objects which appear are potential tubules while in the third image the objects are fat and holes. The examiner's rejection overlooks this important and claimed distinction between the images. Indeed the examiner has not made out a *prima facie* case of obviousness because there has been no factual evidence presented that Cheng discloses the claimed "nature of the objects" which appear in the second image (potential tubules) and the third image (fat and holes. Independent claims 7 and 13 – which include similar features - are likewise non-obvious and patentable over Cheng for this reason as well.

The examiner's position that Cheng reads on step b) because the pixel values which indicate a potential tubule are also pixel values characteristic of fat and holes, i.e. rough textures, is factually insufficient to demonstrate the claim features discussed above. The examiner's position is technically inaccurate because the pixel value characteristics of fat and holes are alike as demonstrated in Figure 5 of Applicants' specification where regions 72 indicate both fat and holes in tubules, but the pixel value characteristics of tubule epithelial layers are quite different to those of fat and holes. (See also Applicants' specification at page 7 line 16 and Cheng page 324 last paragraph last three sentences, referring to tubule bright cores and dark boundaries). Therefore, since there is not a difference in pixel values for the two types of features, Cheng – which evaluates pixel values – would be understood as being unable to distinguish between the features in different images.

b. Cheng does not disclose excluding objects not indicated to have epithelial layers

Independent claims 1, 7 and 13 all include the feature of combining data from the second and third images and identifying holes within tubules "by excluding objects not indicated to have epithelial layers. . . ." (See, e.g., claim 1 step c). The examiner's basis for Cheng disclosing this feature is technically incorrect and, therefore, there is no factual basis for finding this feature in Cheng.

In particular, the examiner states that the analysis taught by Cheng is performed on the initial first objects wherein the first objects are potential or likely tubules and whose pixel values

are characteristic of fat and holes. But in claim 1a) and 1c) potential or likely tubules are not selected from objects having pixel values which are characteristic of fat and holes. The claim instead requires them to be selected from having pixel values which are characteristic of epithelial layers – characteristics where are quite different to those characteristic of fat and holes. Further, the examiner's reliance upon Cheng at page 326, lines 1-6 for disclosing this feature is factually insufficient because all that the recited section discloses is distinguishing background pixels from tubule pixels. There is no disclosure in Cheng of any sorting of pixels or features on the basis – as claimed – that they are or represent epithelial layers. For this reason as well, Cheng does not disclose or suggest all features of the invention claimed in all pending application claims.

c. Cheng does not disclose additional claim features

All pending application claims are further non-obvious and patentable because Cheng does not read on step d), sub-step ii), step e), or step f). Referring to page 326, step D, the examiner contends that Cheng teaches a method of counting the tubule areas. However, as previously discussed, Cheng only counts tubule hole area and not potential tubules (“first objects”) or the area of the tubule epithelial layer surrounding the tubule hole(s), nor does it distinguish tubules with single holes from tubules with multiple holes. Consequently, as has been said all pending claims are non-obvious and patentable over Cheng.

3. Claims 3, 9 and 15 are independently patentable

Claims 3, 9, and 15 are independently non-obvious and patentable. Claims 3, 9 and 15 relate to the third image which distinguishes second objects with pixel values indicating fat and holes: the claims relate to this image being binary. Cheng discloses binary images but does not disclose a binary image which distinguishes second objects with pixel values indicating fat and holes.

4. Claims 4, 10 and 16 are independently patentable

Claims 4, 10 and 16 are also independently non-obvious and patentable. The examiner states that Cheng teaches claims 4, 10 and 16 at page 328. It is respectfully submitted that this statement is entirely lacking in foundation. Claim 4 (similarly claims 10 and 16) relates - broadly speaking - to combining data from the second and third images either by multiplying second

image pixels by respective like-located third image pixels, or by logically ANDing together such pixels.

Cheng page 328 contains no mention whatsoever of:

- d) a second image associated with potential tubules (as per claim 1a)), or
- e) a third image associated with fat and holes within tubules (as per claim 1b)), or
- f) combining data from the second and third images by multiplying or logically ANDing together like-located second and third image pixels.

5. Claims 5, 11 and 17 are independently patentable

Claims 5, 11 and 17 are further independently non-obvious and patentable. Regarding claims 5, 11, and 17, the examiner states that Cheng page 326, step D, teaches grading tubules comparable with that of a physician, i.e. a medical expert as claimed. Here again it is respectfully submitted that this statement is entirely lacking in foundation. In this regard, the only reference to a physician in Cheng step D is in the first and second lines, which state "... for physicians to obtain a score based on tubule grading, they require the total amount of tubule area. This merely states what physicians require not what they do – it contains no disclosure relating to whether the step D tubule grading is or is not comparable with that obtainable by a medical expert.

B. The Rejection of Claims 7 and 9-11 For Obviousness Over Cheng in View of Boon

The examiner rejected independent claim 7 and claims 9-11 – which depend upon claim 7 – for being obvious over Cheng in view of Boon (USP 5,939,278). In particular, the examiner takes the position that Cheng discloses all of the apparatus elements a-f of independent claim 7 except for incorporating a microscope or camera into the apparatus. The examiner relies upon Boon for disclosing this feature of claim 7.

As an initial matter, the Applicant wishes to note that they are not currently relying on the elements of the preamble missing from Cheng for patentability purposes.

Independent claim 7 and dependent claims 9-11 are non-obvious and patentable for at least the same reasons recited above in Section III(A) above with respect to independent claims 1, 7 and 13. Moreover, dependent claims 9-11 are non-obvious and are patentable over Cheng

for the additional reasons recited in Section III(A)(3-5) above.

CONCLUSION

The pending application claims are believed to be ready for patenting for the reasons recited above. Favorable reconsideration and allowance of all pending application claims is courteously solicited.

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